

## **REMARKS**

Applicants have carefully examined the Office Action of December 2, 2008, in which claims 74, 77-84, 87-91, 130-133 and 140-153 are pending in the application and have been rejected. Applicants respectfully request re-examination in light of the above amendments and following remarks.

### **Objections and 35 USC 112 Rejections Pertaining to Claim 149**

Items 2, 3 and 5 in the Office Action pertain to claim 149. In Item 2, the amendment of September 11, 2008 was objected to under 35 USC 132(a) as introducing new matter, to wit: “the region is attached to a proximal waist of the balloon” of claim 149. In Item 3, claim 149 was objected to because of certain informalities, to wit: “the term ‘waist’ may cause some confusion/difficulty in interpreting the claim language because the ‘proximal waist of the balloon’ of claim 149 appears to be the same as the “proximal end of the balloon” of claim 74.” And in item 5, claim 149 was rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement, to wit “the recitation ‘the region is attached to a proximal waist of the balloon’ of claim 149 does not appear to be supported in the specification as originally filed” and claim 149 was also rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, to wit “the structure Applicant intends to recite by “the region is attached to a proximal waist of the balloon’ cannot be ascertained.”

Because these objections and rejections are all highly interrelated, applicants intend to discuss them together, Applicants hereby traverse the above objections and rejections.

The term “waist” has a meaning to those of skill in the medical device arts. Balloons such as are used in angioplasty and stent delivery usually include a central cylindrical portion between two conical portions, as shown for example in Figure 1 of the instant application. Shorter cylindrical portions extend from these conical portions and are in contact with other portions of the catheter and are affixed to these other portions. These shorter cylindrical portions are referred to as waists. The proximal shorter cylindrical portion is the proximal

waist and the distal shorter cylindrical portion is the distal waist. There is thus no ambiguity or obscurity with regard to the use of the term waist in the present context.

Thus, with regard to the new matter objection of Item 2, it can be seen that no new matter was in fact introduced. For example, in Figure 1, item 170 is a region attached to the proximal waist of the balloon 175. That item 170 can be considered a region that comprises a polyamide as claimed in claim 74 is clear with respect to the specification. For example, see paragraphs 71, 75, 81, 88, etc. Applicants therefore submit that the amendment of September 11, 2008 complies with 35 USC 132(a) and request withdrawal of this objection.

With regard to the Item 3 objection, it can consequently be seen that the use of the term waist causes no difficulty or confusion in interpretation. Claim 74's recitation "wherein the region is at least partially disposed proximally of the proximal end of the balloon" defines a spatially relationship between the region and the balloon. Claim 149's recitation "wherein the region is attached to a proximal waist of the balloon" defines further detail.

With regard to the 35 USC 112 rejections of claim 149 in Item 5, applicants respectfully disagree with the Examiner's interpretation of the phrase "is attached to." This phrase does not imply (or preclude) the region from being a separate component of the catheter. In claim 74, the catheter includes a catheter shaft and a balloon and the "catheter shaft includes a region." Therefore, reciting in claim 149 that "the region is attached to a proximal waist of the balloon" presents no difficulty. It simply means that the region of the catheter shaft is attached to a proximal waist of the balloon. As the attachment of the catheter shaft to the balloon is clearly supported by the specification (see Figure 1) as filed and, as discussed above, item 170 of Figure 1 can be the region as claimed, the attachment of the region to a proximal waist of the balloon is also supported by the specification as filed. Moreover, as discussed above, the meaning of claim 149 is sufficiently clear. Accordingly, applicants submit that claim 149 complies with 35 USC 112, first and second paragraphs, and request withdrawal of this rejection.

#### **Other 35 USC 112 Rejections**

Claims 131 and 133 were also rejected under this section. These claims have been cancelled, rendering the rejection moot.

**35 USC 103 Rejections**

Claims 74, 77-79, 84, 87-88, 130, 132, 140, 142, 144-150 and 152 were rejected under 35 USC 103(a) as being unpatentable over Callol, USPN 6,709,440. Applicants respectfully traverse the rejection.

The Office Action notes that “Callol et al. fails to explicitly teach that the tensile strength of the polyamide is at least about 21,000 psi, and the recited thickness of the wall shaft” and that Callol teaches that the polyamide of the shaft has a tensile strength of at least 15,000 psi. Page 5. Callol apparently does not recite any wall thickness dimensions.

It is argued in the Office Action that “it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the tensile strength of the polyamide used for the material of the shaft in order to achieve the desired degree of strength of the shaft wall depending on the particular desired end result depending on the desired use, since it has been held that discovering an optimum value of a results effective variable involves only routine skill in the art in the absence of unexpected results.” Applicants respectfully disagree.

Tensile strength is not a variable; it is a material property that is changed only by material selection and processing. In contrast, a variable is ‘a quantity that can assume any set of values’ or “a symbol (like x or y) that is used in mathematical or logical expressions to represent a variable quantity.” <http://onelook.com/?w=variable&ls=a>. Thus the examples used in MPEP 2144.05, pertaining to optimizations, use as examples ratios (In re Antonie), percentages (In re Boesch), temperatures, dimensions and so forth. These are parameters that can be easily varied to produce a tangible result. In contrast, when one selects a desired tensile strength for a component, there is no certain method of being able to produce a product having that desired property because a material having all desired properties may not exist. Thus one cannot simply vary tensile strength to achieve a desired strength.

Moreover, the claimed property of “at least 21,000 psi” is not disclosed by Callol. Callol teaches that the polyamide has a tensile strength of at least 15,000 psi. This is not a disclosure of an enabled range because there is no upper limit. We know, for example, that a polyamide having a tensile strength of 50,000,000 psi is not disclosed, because this quantity is above the theoretical top limit of the tensile strength of carbon nanotubes, which have the

highest tensile strength of any material yet measured. One cannot therefore reasonably say that any tensile strength above 15,000 psi is disclosed.

And creating a polyamide with a tensile strength of 21,000 psi is not done through routine experimentation. As discussed above, tensile strength is not a variable like a percentage or a temperature, which may be easily changed. One changes the quantity of a material added to change the percentage of that material in the product and one uses a heating or a cooling unit to obtain a desired temperature. Creating a polyamide with desired properties is not routine; there is no certain procedure an experimenter can follow to obtain desired results. As applicants say in paragraph 121 of the application as published:

Without wishing to be bound by theory, it is believed that the longitudinal and radial stretch-blown processes described herein can result in a relatively strong tube-shaped catheter component. In particular, it is believed that the use of a longitudinal strain and/or pressure during the stretch-blowing portion of the process ultimately results in a tube-shaped catheter component that is relatively thin, but that has, for example, a burst pressure and/or load at break that is comparable to those achieved by tube-shaped catheter component preparation processes that result in relatively thick tube-shaped catheter components (e.g., processes in which a longitudinal strain and/or pressure is not used). It is believed that longitudinal and radial stretch-blowing result in relatively thin tube-shaped catheter components that have relatively large tensile strengths and/or relatively large hoop stresses.

Because the tensile strength of a polyamide cannot be varied as desired through routine experimentation, “a polyamide having a tensile strength of at least about 21,000 psi” as recited in claim 74 is not obvious over Callol, which teaches only a polyamide with a tensile strength of greater than 15,000 psi. Applicants accordingly submit that this claim is in condition for allowance. As claims 77-79, 130, 140 and 144-150 depend therefrom and contain additional elements, applicants submit that these claims are also in condition for allowance.

Claim 84 recites “a polyamide having a hoop stress of at least about 3300 psi.” For reasons similar to those discussed above with respect to claim 74, applicants submit that this

claim is also non-obvious over Callol. The creation of a polyamide with the recited property involves more than routine experimentation as the hoop stress is not a variable that can be easily altered; it is a property whose discovery involves more than routine experimentation. Applicants therefore submit that claim 84 is in condition for allowance. As claims 87-88, 132, 142 and 152 depend from claim 84 and contain additional elements, applicants submit that these claims are also in condition for allowance.

**Conclusion**

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance, issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,  
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By their Attorney,

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